Cefazolin, 1 gram fits all?

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Objective: 1) to assess whether adequate serum and interstitial fluid levels of cefazolin are reached during surgery in obese and non-obese patients, 2) to develop a population pharmacokinetic model for cefazolin which allows the characterization of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON31576

Source
ToetsingOnline

Brief title
Cefazolin, 1 gram fits all?

Condition

- Bacterial infectious disorders

Synonym
cefazolin concentrations in plasma and interstitial fluid

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cefazolin, pharmacokinetics, surgical prophylaxis

Outcome measures

Primary outcome

Main study parameters/endpoints: serum and interstitial fluid concentration of cefazolin at specific timepoints before and during surgery until 2 hours after woundclosure.

Secondary outcome

to implement the results in daily practice

Study description

Background summary

Rationale: The basic principle of surgical antibiotic prophylaxis is the attainment of adequate levels of antibiotic in the tissue before and throughout the period of potential bacterial contamination. The duration and adequacy of antibiotic levels in the tissues is mainly determined by the pharmacokinetic characteristics of the antibiotic, e.g. volume of distribution, clearance and the rate and extent by which the drug penetrates in the target tissue.
The Dutch guideline for perioperative antibiotic prophylaxis recommends a standard dose of 1 gram of cefazolin for most surgical procedures. Although this dose may be sufficient for most patients, it is however not clear whether adequate antibiotic concentrations are reached in obese patients. In fact, some studies have demonstrated that obesity is a risk factor for post-operative wound infection. Furthermore, there is limited information with respect to the effect of overweight on pharmacokinetics and clinical efficacy of most antimicrobials.

Study objective

Objective: 1) to assess whether adequate serum and interstitial fluid levels of cefazolin are reached during surgery in obese and non-obese patients, 2) to develop a population pharmacokinetic model for cefazolin which allows the characterization of the relationship between body size and the pharmacokinetic parameters and 3) to implement the results in daily practice.

Study design

Study design: Observational cohort study (Sept 2007 - Sept 2008).

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks associated with participation are minimal since perioperative antibiotic prophylaxis is administered in accordance with the Dutch Guidelines. During surgery a total extra volume of approximately 30-40 ml blood will be drawn. In 15 patients a subcutaneous microdialysis catheter will be placed for determination of interstitial fluid concentrations. The burden of this catheter is minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

· Age => 18 years
· Surgical procedures:
hip of knee surgery
osteotomy
surgery to cruciate ligaments
neurosurgery
· Cefazolin prophylaxis (1 gram)
· Signed informed consent

Exclusion criteria

· Age < 18 years
· Pregnancy
· Undergoing any form of dialysis
· Patient had received a dosage of cefazolin more than 2 hours before incision
. known allergy or hypersensitivity to cephalosporins

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Kefzol
Generic name:	cefazolin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-09-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-02-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-07-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-004211-60-NL
CCMO	NL19175.078.07